## REMARKS

Claims 1-36 are present in the instant application. No claims have been indicated to be allowable.

**Claims Objections:**

**35 USC 102**

Claims 1-5, 8-9, 11-23, 26-27 and 29-36 stand rejected under 35 USC 102 as unpatentable over Ojima (US 7,029,717).

Examiner states that Ojima discloses compositions with one or more substances such as protein hydrolysates and amino acids where sucralose comprises 1% of the compositions. Examiner extends the reference to conclude sucralose is masking the taste of the amino acid, thereby encompassing the method claims.

Applicant notes that the composition of Ojima requires the "combining" of sucralose with a purine base (Claim 1) or with many other products including flavonoids (Example 7, 8), fatty acid esters (Example 9), acids (Example 10-13, 19-20), phosphates (Example 14-15), amino acids (Example 17) and other materials. In every example the product of Ojima does not use sucralose but a reaction product created when the purine base (or other product, see all examples) is heated with sucralose for a period of 1 hr at 100°C - 150°C. The resulting compound manufactured from sucralose (**not sucralose itself**) is superior in sweetness intensity and quality in every example. It is apparent to one skilled in the art, that the nitrogenous base (or numerous other compounds) is reacted with the sucralose to improve its flavor characteristics and that no nitrogenous base remains present in an unreacted form. Thus, sucralose is not present for taste masking purposes in the compounds of Ojima but rather forms a reaction product of sucralose in which the added product was present in much smaller quantities (0.001 to 1 part per 1 part of sucralose). The proteins (col.7, lines 7-23) and amino acids (col. 7, lines 24-37) **are not present** in the tasted material, since they have been reacted (e.g., Example 17) with an excess of sucralose to form the reaction product which gives the superior sweetness and

intensity illustrated in the examples. **Again, no methionine (Example 17) is present in the tasted mixture, but a reaction product of methionine and sucralose, superior in taste to sucralose!** Taste masking of the nitrogenous base is not achieved as the nitrogenous base is no longer present as an unreacted species in the composition of Ojima and no methionine is present in the composition since it is the limiting reagent in the reaction (see levels used in other examples and compare the 0.1 part used in Example 17). Levels of nitrogenous base equal to that of sucralose were reacted in some Examples, however, the nitrogenous base was never placed in excess or tasted by the panel as in each example the sucralose had undergone a reaction period at elevated temperature. The composition tasted is not one in which an amino acid is present (but a reaction product of the amino acid and the sucralose) and thus the composition does not reflect on the present invention wherein sucralose is used as a taste masking agent for the amino acids. The composition cited by the Examiner in Ojima is rather one for production of the superior tasting product of Ojima.

Thus, Ojima does not anticipate the claims as it does not teach a composition containing sucralose and an amino acid, protein or protein hydrolysate, but teaches a composition for a reaction product formed by heating at 100°C or above, for one hour or more in which an excess of sucralose is combined with an amino acid, protein or protein hydrolysate. This new combination product is superior in sweetness intensity and quality to sucralose itself, but in no instance would one skilled in the art suspect that the composition of the amino acid, protein or protein hydrolysate remained present in an unreacted state since increasing quantities of the amino acid, protein or protein hydrolysate resulted in further intensification of the sweetness of the reacted materials.

Claims 1-6 and 19-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Golini. Golini does not use sucralose for taste masking, but for sweetness, a well known use, as seen in paragraph (0028), where it is not included in the formulation but it is later suggested that flavors may be added for taste and sweetness. No special effect of taste masking is implied or specifically stated. As seen in the current application, neither aspartame nor saccharine masks the taste of the amino acids, however in [0020], these are used for the same purpose as sucralose, clearly indicating that the sucralose of Golini is used only for sweetness and not for taste

masking. In fact, the word "mask" does not even appear in the Golini application! At [0029], no sweetener is even used but rather flavors are added, thus additionally showing that sucralose is not used as a taste masking agent.

Claims 1, 5, 19 and 23 have been amended to delete reference to creatine, even though taste masking is not the issue at hand but rather sweetness is.

**Claim Rejections - 35 USC§103 - Obviousness**

Office Action Item 1

Claims 7, 10, 25 and 28 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Ojima et al (US 7,029,717) in view of Newsholme et al(US 5,639,731).

As stated above, Ojima does not reference the use of sucralose in conjunction with amino acids for purposes of improving flavor or sweetness, but reacts excess sucralose at above 100°C for extended periods of time with various materials, including amino acids, proteins, and protein hydrolysates, to provide a product, **other than sucralose itself**, with superior sweetening intensity and quality to sucralose. Neither the amino acids, proteins, or protein hydrolysates are ever used in excess of the quantity of amino acids, proteins or protein hydrolysates, nor is sucralose itself used except as a reactant showing the reaction product formed to be superior to sucralose as a sweetener. In addition, the quantity of sucralose used by Ojima is equal to or up to 1000 times as much as the amino acids with which the sucralose is reacted. Even if one skilled in the art mistakenly thought that Ojima used sucralose (and not its reaction product) were used by Ojima, one skilled in the art would immediately recognize that such combinations could never be used in conjunction with the product of Newsholme. Thus, the combination with Newsholme is unjustified as one part of the combination Ojima fails to pertain to the use of sucralose as a taste masking agent. It is further unjustified for the quantities of sucralose required by Ojima in manufacturing his new product (**not sucralose**).

**35 USC§103 - Obviousness Office Action Item 2**

Claims 1-5, 8-9, 11-23, 26-27 and 29-36 stand rejected under 35 USC 103 (a) as unpatentable over Kurtz et al., 5,639,788, in view of Cherukuri et al., 5,013,716.

Kurtz (col 6, line 42), notes that "The use of additives to debitter eatables has been

attempted by others" and then goes on to say it has been unsuccessful in the case of the acidic amino acids (col 7, line 4). This clearly shows that the idea that one product will work in all cases is unfounded, their being a diversity of bitter principles (col 7, line 1) and additives. Citation of the existence of a known "bitter principle" and the fact that others have suggested that some bitter principles may be overcome by additions of still other substances, ignores the very teaching of Kurtz that this is not so (Col 6, line 66 to col 7, line 5). As shown in the current application, the amino acids as a class are not covered as arginine is an exception to the finding that sucralose alone is sufficient to cover its sour aftertaste (Table 1).

Cherukuri et al., experts in the field, retained by a major drug firm for their research expertise and knowledge, associated with experienced patent attorneys of long history and high expertise in the broad claims required by fundamental inventions, disclose every possible medicinal material they thought could possibly be masked with their invention (a laundry list of 14 broad classes including literally hundreds, if not thousands of drugs) and the fact that they did not disclose the use of sucralose to mask the taste well known, extremely offensive aftertaste of amino acids, amino acid analogs, polypeptides, peptides or proteins, excluding arginine, and such an omission from such a lengthy list by these experts in the field clearly indicates that they did not believe nor was it obvious to them, to use sucralose to taste mask these clearly omitted items, specifically, amino acids, amino acid analogs, polypeptides, peptides and proteins. Experts in the field acknowledge that these materials have a noxious taste that is significantly different from others, e.g. Kurtz (col 7, lines 2-5).

As pointed out in answer to an earlier rejection, Blase et al., 5,409,907 (filed December 16, 1993), in reviewing the status of the art states, "a common problem associated with liquid pharmaceutical dosage forms is the often disagreeable taste of a drug that may manifest itself when the drug is in a liquid dosage form. Sometimes, the taste of the drug in the dosage form may be overpowered by adding sweeteners or flavoring agents to the liquid dosage. These agents mask the bitter or unpleasant taste of drugs. **However, these agents are not totally effective in concealing the unpalatable taste of pharmaceuticals.**"(Col 1, lines 41-49). Thus, it is clear that at the time of this filing (after the Cherukuri et al., issue date), the ability of sweeteners alone was known **not** to be sufficient to effectively mask the unpalatable taste of

pharmaceuticals, but in addition required the use of the minimal water suspensions of the invention.

Thus, one part of the combination of patents cited does not teach taste masking for these materials as obvious and should not be cited against applicant's case.

**Office Action Item 3**

Claims 1-5, 8-9, 11-23, 26-27 and 29-36 stand rejected under 35 USC 103 (a) as unpatentable over Kodera et al., 6,455,273 B1, in view of Cherukuri et al., 5,013,716. Examiner again makes the invalid connection between a know bitter taste of protein hydrolysates and the fact that sucralose was known to mask some bitter tastes.

Cherukuri et al., experts in the field, retained by a major drug firm for their research expertise and knowledge, associated with experienced patent attorneys of long history and high expertise in the broad claims required by fundamental inventions, disclose every possible medicinal material they thought could possibly be masked with their invention (a laundry list of 14 broad classes including literally hundreds, if not thousands of drugs) and the fact that they did not disclose the use of sucralose to mask the taste well known, extremely offensive aftertaste of amino acids, amino acid analogs, polypeptides, peptides or proteins, excluding arginine, and such an omission from such a lengthy list by these experts in the field clearly indicates that they did not believe nor was it obvious to them, to use sucralose to taste mask these clearly omitted items, specifically, amino acids, amino acid analogs, polypeptides, peptides and proteins. Experts in the field acknowledge that these materials have a noxious taste that is significantly different from others, e.g. Kurtz (col 7, lines 2-5).

As pointed out in answer to an earlier rejection, Blase et al., 5,409,907 (filed December 16, 1993), in reviewing the status of the art states, "a common problem associated with liquid pharmaceutical dosage forms is the often disagreeable taste of a drug that may manifest itself when the drug is in a liquid dosage form. Sometimes, the taste of the drug in the dosage form may be overpowered by adding sweeteners or flavoring agents to the liquid dosage. These agents mask the bitter or unpleasant taste of drugs. **However, these agents are not totally effective in concealing the unpalatable taste of pharmaceuticals.**"(Col 1, lines 41-49). Thus, it is clear that at the time of this filing (after the Cherukuri et al., issue date), the ability of

sweeteners alone was known **not** to be sufficient to effectively mask the unpalatable taste of pharmaceuticals, but in addition required the use of the minimal water suspensions of the invention.

**Office Action Item 4**

Claims 1-5, 8-9, 11-23, 26-27 and 29-36 stand rejected under 35 USC 103 (a) as unpatentable over Daravingas et al., 6,235,320 in view of Cherukuri et al., 5,013,716. Daravingas et al., disclose that amino acids, protein hydrolysates, peptides and polypeptides have a bitter taste as stated by Applicant [0002].

Cherukuri et al., experts in the field, retained by a major drug firm for their research expertise and knowledge, associated with experienced patent attorneys of long history and high expertise in the broad claims required by fundamental inventions, disclose every possible medicinal material they thought could possibly be masked with their invention (a laundry list of 14 broad classes including literally hundreds, if not thousands of drugs) and the fact that they did not disclose the use of sucralose to mask the well known, extremely offensive aftertaste of amino acids, amino acid analogs, polypeptides, peptides or proteins, excluding arginine, and such an omission from such a lengthy list by these experts in the field clearly indicates that they did not believe nor was it obvious to them, to use sucralose to taste mask these clearly omitted items, specifically, amino acids, amino acid analogs, polypeptides, peptides and proteins. The failure of sucralose alone to mask the taste of arginine as pointed out in Applicant's specification clearly shows that amino acids as a class are not taste masked by sucralose. Experts in the field acknowledge that amino acids have a noxious taste that is significantly different from others, e.g. Kurtz (col 7, lines 2-5).

As pointed out in answer to an earlier rejection, Blase et al., 5,409,907 (filed December 16, 1993), in reviewing the status of the art states, "a common problem associated with liquid pharmaceutical dosage forms is the often disagreeable taste of a drug that may manifest itself when the drug is in a liquid dosage form. Sometimes, the taste of the drug in the dosage form may be overpowered by adding sweeteners or flavoring agents to the liquid dosage. These agents mask the bitter or unpleasant taste of drugs. **However, these agents are not totally effective in concealing the unpalatable taste of pharmaceuticals.**"(Col 1, lines 41-49). Thus,

it is clear that at the time of this filing (after the Cherukuri et al., issue date), the ability of sweeteners alone was known **not** to be sufficient to effectively mask the unpalatable taste of pharmaceuticals, but in addition required the use of the minimal water suspensions of the invention.

**Conclusion**

For all the reasons given above, Applicant respectfully submits that the claimed distinctions are of patentable merit under Section 103. Accordingly, applicant submits that this application is now in full condition for allowance, which action Applicant respectfully solicits.

Respectfully,

Gary J. Calton

Applicant Pro Se

**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8**

Pursuant to 37 C.F.R. §1.8, I hereby certify that I have a reasonable basis to expect that this correspondence will be deposited with the United States Postal Service on or before the dated indicated, as Express Mail EO 930 330 570 US in an envelope addressed to Commissioner of Patents and Trademarks, P.O. Box 1450 Alexandria, VA 22313-1450

_____ _____

Date Signature